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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
RAO, SAVITHA M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,228	STOFFELS, PAUL	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are currently pending in the instant application and are subject to a lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Note: An instant claim 24 is drawn to a non-statutory subject matter. They are use claims and therefore, the claimed invention is not supported by either a asserted utility or a well established utility. It is drawn towards the use of a combination for the manufacture of a medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Accordingly, in the instant restriction requirement claim 24 is being included in groups I -III, IV-VI and VII-IX below drawn towards a product, method of manufacturing and method of use respectively. It is incumbent upon the applicant to clarify the invention to which the claims are drawn to.

I. Group I: Claims 1, 2, 5, 6, 7, 9, 10, 12, and 14, 16-24 are drawn to a combination and pharmaceutical formulation comprising TMC278 and a **nucleoside** reverse transcriptase inhibitor. Further election of species as

set forth below in election of specie requirement 1 and 2 are required upon electing this invention.

II. Group II: Claims 1, 3, 6, 7, 8 19-24 is drawn to a drawn to a combination and pharmaceutical formulation comprising TMC278 and a **nucleotide** reverse transcriptase inhibitor.

III. Group III. Claims 1, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 19-24 drawn to a combination and pharmaceutical formulation comprising TMC278, a **nucleoside** reverse transcriptase inhibitor and a **nucleotide** reverse transcriptase inhibitor. Further election of species as set forth below in election of specie requirement 1 is required upon electing this invention.

IV. Group IV Claim 24 is drawn to a method of manufacturing a medicament using the combination comprising TMC278 and a **nucleoside** reverse transcriptase inhibitor as detailed in **Group I.** Further election of species as set forth below in election of specie requirement 1 and 2 are required upon electing this invention.

V. Group V: Claim 24 is drawn to a method of manufacturing a medicament using the combination comprising TMC278 and a **nucleotide** reverse transcriptase inhibitor as detailed in **Group II.**

VI. Group VI. Claim 24 is drawn to a method of manufacturing a medicament using the combination comprising TMC278, a **nucleoside** reverse transcriptase inhibitor and a **nucleotide** reverse transcriptase inhibitor as detailed in **Group III**. Further election of species as set forth

below in election of specie requirement 1 is required upon electing this invention.

VII. Group IV Claim 24 is drawn to a method of prevention of HIV infection or transmission by treatment with a **nucleoside** reverse transcriptase inhibitor as detailed in **Group I.** Further election of species as set forth below in election of specie requirement 1 and 2 are required upon electing this invention.

VIII. Group VIII: Claim 24 is drawn to a method of prevention of HIV infection or transmission by treatment with the combination comprising TMC278 and a **nucleotide** reverse transcriptase inhibitor as detailed in **Group II.**

IX. Group IX. Claim 24 is drawn to a method of prevention of HIV infection or transmission by treatment with the combination comprising TMC278, a **nucleoside** reverse transcriptase inhibitor and a **nucleotide** reverse transcriptase inhibitor as detailed in **Group III**. Further election of species as set forth below in election of specie requirement 1 is required upon electing this invention.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single

general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a).

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Groups I-IX lack unity of invention under 37 CFR 1.475 since the three groups (I-IX) are not unified by the same or corresponding special feature as detailed below.

The special technical feature in Group I is combination of TMC278 with a nucleoside reverse transcriptase inhibitor which are analogs of the normal nucleosides RT uses to synthesize viral DNA except they lack a normal 3'OH, and as a consequence acts as chain terminators when incorporated into viral DNA.

The special technical feature in Group II is combination of TMC278 with a nucleotide reverse transcriptase inhibitor which acts by binding to the active site of reverse transcriptase and competes with incoming nucleotides.

The special technical feature in Group III is combination of TMC278 with a nucleoside reverse transcriptase inhibitor which acts as chain terminators and a nucleotide reverse transcriptase inhibitor which acts by binding to the active site of reverse transcriptase and competes with incoming nucleotides.

The special technical feature in Group IV is the method of using the combination of Group I to manufacture a medicament which involves combining the combination of Group I with a vehicle and other excepients.

The special technical feature in Group V is the method of using the combination of Group II to manufacture a medicament which involves combining the combination of Group II with a vehicle and other excepients.

The special technical feature in Group VI is the method of using the combination of Group III to manufacture a medicament which involves combining the combination of Group III with a vehicle and other excepients.

The special technical feature in Group VII is the method of using the combination of Group I for prevention of HIV infection or its transmission, which involves identifying a patient population, determining dosage requirements and routes of administration, actual process of administering the medicament to the patient and patient monitoring.

The special technical feature in Group VIII is the method of using the combination of Group II for prevention of HIV infection or its transmission, which involves identifying a patient population, determining dosage requirements and routes of administration, actual process of administering the medicament to the patient and patient monitoring

The special technical feature in Group IX I is the method of using the combination of Group III for prevention of HIV infection or its transmission, which involves identifying a patient population, determining dosage requirements and routes of administration, actual process of administering the medicament to the patient and patient monitoring

Accordingly there is no same or corresponding special technical features unifying Groups I to IX and thereby they lack unity.

Furthermore even if unity of invention under 37 CFR 1.475(a) is not considered lacking which in this case they are as described above, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out the said process.

And according to 37 CFR 1.475(c): if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since in the instant application the claims are drawn to patentably distinct inventions, based on, three different combination and three different methods of manufacturing as shown above, and according to 37 CFR 1.475(e): the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claims.

The group's I-IX, therefore, lack unity of invention.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1. Election of Specie Requirement 1

This specie election applies to the Groups I, III, IV ,VI, VII and IX detailed in the restriction requirement above.

Applicant is required, in reply to this action, to elect single disclosed specie (A or B or C) of the nucleoside reverse transcriptase inhibitor from those detailed below:

Specie A: emtircitabine

Specie B: lamivudine

Specie C: abacavir

Claim 9 is generic to the species above.

The species are structurally divergent, differ in their physical, chemical and biological properties and activities and thereby require searching in different class/subclasses and use of different search queries. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii)identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered

nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

2. Election of Specie Requirement 2

This specie election applies to Groups I, IV and VII detailed in the restriction requirement above.

Applicant is required, in reply to this action, to elect single disclosed specie (D or E) which is presence or absence of the second nucleoside reverse transcriptase inhibitor (as recited in instant claims 5,16,17 and 18) detailed below:

Specie D: Absence of the second **nucleoside reverse transcriptase** inhibitor

Specie E: Presence of the second **nucleoside reverse transcriptase** inhibitor

Claim 5 and 9 are generic to the above species.

The species are structurally divergent, differ in their physical, chemical and biological properties and activities and thereby require searching in different class/subclasses and use of different search queries. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii)identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do

so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 8 am to 5 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614